

REJECTION UNDER 35 U.S.C. § 103 IS IN ERROR

Claims 1-4 and 8-27 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,713,181 to Kmiec et al. ("Kmiec") in view of U.S. Patent No. 5,204,253 to Sanford et al. ("Sanford"). According to the Examiner:

Given the recognition of those of ordinary skill in the art of the value of developing a method for correcting genetic diseases that are mainly controlled by a single point mutation or to develop a method for screening transgenic plants containing the desirable traits, it would have been obvious at the time the invention was made to use the teaching of Sanford et al. for delivering by particle bombardment the genes taught by Kmiec et al. in order to produce a method for making localized mutations as claimed in the instant invention. Furthermore, the number of bases used in the sequence of the homologous or intervening regions, the choice of gene used, the method of adhering and transformation are a matter of choice unless the criticality of proof is provided.

Applicants respectfully disagree with the Examiner's rejections.

Applicants point out that the pending claims are directed to methods for making a localized mutation causing a desired trait in a target gene in a plant cell by introducing by particle bombardment a recombinagenic oligonucleobase. The methods of the present invention allow for the site-specific change of a nucleotide in a target gene in a plant cell. Applicants note that the recombinagenic oligonucleobases of the present invention are separate and distinct from plasmids, which comprise only DNA-type nucleotides and normally contain open reading frames linked to expression control sequences and origins of replication for replication of the plasmid in one or more cell types. As explained in the specification at pages 4-7, the recombinagenic oligonucleobases, *inter alia*, have two complementary strands, in which one of the strands contains a segment of RNA-type nucleotides.

Applicants point out that Kmiec does not explicitly disclose transformation of plant cells with recombinagenic oligonucleobases using particle bombardment. Sanford teaches the transformation of cells, including plant cells, with plasmids, not recombinagenic oligonucleobases.

A rejection for obviousness is improper when there is nothing in the cited prior art references, either singly or in combination, to suggest the desirability of the claimed subject matter. For a rejection of claimed subject matter as obvious in view of a combination of prior art references to be upheld, (1) the prior art must have suggested to those of ordinary

skill in the art that they should make the claimed composition or device or use the claimed method, as the case may be; and (2) the prior art must have revealed that in so doing, those of ordinary skill would have had a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Applicants point out that there is no reasonable expectation of success that the particle bombardment method of Sanford would allow for the successful making of a localized mutation in a desired gene in a plant cell. Applicants point out that it is well known in the art that plasmids transformed into cells by the method of Sanford are randomly inserted into the genome of the cell due to the physical nature of this particular method. In view of this knowledge Applicants respectfully submit that Sanford actually teaches away from the presently claimed methods of making a localized mutation in a target gene; the method is unsuccessful if the oligonucleobase inserts into the target gene.

Applicants respectfully submit that the Examiner seems to stating no more than it would have been obvious to try to make a localized mutation in a target gene in a plant cell by transforming the plant cell with a recombinagenic oligonucleobase via particle bombardment. An obvious to try standard is not a legally sufficient basis to sustain a rejection under 35 U.S.C. § 103. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). Further, the Examiner is using impermissible hindsight reconstruction based on knowledge of Applicants' invention. Applicants respectfully suggest that the Examiner is employing, perhaps unconsciously, a hindsight reconstruction in combining the references to make his alleged *prima facie* case of obviousness. Such hindsight reconstruction does not meet the legal standard for obviousness. "A single line in a prior art reference should not be taken out of context and relied upon with the benefit of hindsight to show obviousness." *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 230 USPQ 416 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

It is error to reconstruct the patentee's claimed invention from the prior art by using the patentee's claim as a "blueprint". When prior art references require selective combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight obtained from the invention itself.

*Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543 (Fed. Cir 1985).

Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow Chemical Co.*, 5 USPQ2d 1529 (Fed. Cir 1988) (emphasis added). There are no suggestions in the references cited to combine the teachings of these references to produce the methods of the present invention, *i.e.*, making a localized mutation in a target gene in a plant cell employing the transformation method of Sanford, *i.e.*, particle bombardment. "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *Carella v. Starlight Archery*, 231 U.S.P.Q. 644 (Fed. Cir. 1986).

Applicants believe that the Examiner is using the disclosure of the present invention as the suggestion to combine the references. "There must be a reason or suggestion in the art for reflecting the procedure used, other than knowledge learned from the applicant's disclosure." *In re Dow Chemical Co.*, 5 USPQ2d (Fed. Cir. 1988). At most, in view of these disclosures and a lack of a suggestion to combine them, one skilled in the art might find it obvious to try to use the particle bombardment method of transformation to make a targeted mutation in a desired gene in a plant cell. However, obvious to try is not the standard as set forth under 35 U.S.C. § 103. "[The Court of Appeals for the Federal Circuit has] consistently held that obvious to try is not to be equated with obviousness under 35 U.S.C. § 103." *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923 (Fed. Cir. 1990). "[T]his is not the standard of 35 U.S.C. § 103". *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987). Applicants, therefore, respectfully submit that the Examiner has not met his burden in setting forth a *prima facie* case of obviousness and as such the rejection, based on 35 U.S.C. §103 for obviousness, should be withdrawn.

### **CONCLUSION**

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. Claims 1-4 and 8-27 fully meet all statutory requirements for patentability. Withdrawal of the Examiner's rejections and early allowance and action for issuance is respectfully requested.

Applicants respectfully request that the Examiner call the undersigned at (212) 790-9090 if any questions or issues remain.

Respectfully submitted,

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Enclosures